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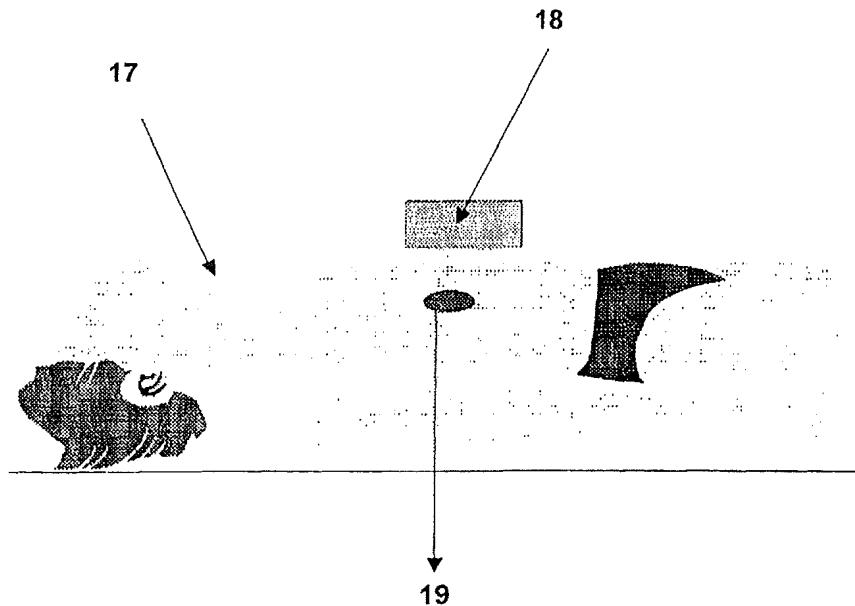
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(54) Title: NAVIGATING AND MANEUVERING OF AN IN VIVO VEHICLE BY EXTRACORPOREAL DEVICES



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(57) Abstract: A device for mobilizing, rotating and maneuvering an in vivo vehicle introduced into a subject by extracorporeal devices which control the position and motion of such a vehicle by detection and modulation of the strength and direction of the electromagnetic field vector of the vehicle. This invention employs a series of pulses, with specific characteristics over time, to induce magnetic field changes. The changes that result from the vehicle movement are measured and used to calculate the location and movement of the vehicle. A system and method for controlling the movement of the vehicle are also provided.



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NAVIGATING AND MANEUVERING OF AN IN VIVO VEHICLE BY EXTRACORPOREAL DEVICES

FIELD OF THE INVENTION

5 The present invention relates to a device and system for mobilizing, rotating and maneuvering of an *in vivo* vehicle by extracorporeal devices, and in particular to mobilizing, and controlling the movement of an *in vivo* vehicle by remote activation of force and moment of magnetic or electric fields.

10 BACKGROUND OF THE INVENTION

High resolution imaging of lumens and epithelial surfaces of internal organs is required for many different types of diagnostic procedures. Among imaging techniques employed in modern medical practice are X-ray, ultrasound (US), magnetic resonance imaging (MRI), computerized tomography (CT) and positron emission tomography (PET). These methods rely 15 on measuring and recording physical parameters of internal body parts, and transforming these parameters into informative images. These methods require expensive equipment, not all of which is available in many small and medium size medical centers (especially MRI). These diagnostic procedures also require several skilled practitioners (doctors, nurses and operators) to perform the procedure and interpret the image outputs. All of these factors together lead to 20 relatively high costs of such procedures to the medical health insurance system, while their frequency of use is increasing.

Direct visual observation of internal body organs, like blood vessels, the gastrointestinal tract (GI), lungs, pelvis and abdomen, have significant advantages over indirect diagnostic imaging mainly because it allows real time observation, and the possibility of obtaining a 25 sample for histological examination. The most common method of directly examining the upper or lower GI tract, as well as for examining other body cavities, is endoscopy. The physician has a real time image (either directly or via an external monitor) of the surface or lumen under investigation. The picture recorded in the endoscopic procedure is produced by optical and electro-optical instruments that are inserted into the body in the form of a long, semiflexible 30 tube. One disadvantage of endoscopy and similar methods is the requirement of a direct connection (rigid or flexible) from the examined area to the detector system outside of the body. Another disadvantage is that the instrument does not move easily through the body cavities,

causing discomfort to the patient and putting him at risk for complications such as bleeding and infection, accompanied by significant inconvenience.

An alternative to endoscopy is a method which employs a wireless vehicle inside the body capable of gathering and transmitting image data to outside the body. Such a method is taught by US Patent Nos. 4278077, 5217449, 5604531, and 6240312 which describe *in vivo* camera systems for examination of internal body lumens. Such an imaging and transmitting device can be any *in vivo* vehicle that can transmit information outside the body. The movement of such devices depends on external direct aiming (via endoscope or catheter), or, more commonly, on natural movement such as blood flow or peristaltic motion of the digestive muscles.

Relying on peristaltic bowel movement has an inherent disadvantage. When the vehicle is in the colon, the peristaltic movement occurs only if the colon is filled with some fecal content. However, when the colon is filled or partially filled with feces, the observation capability is dramatically reduced. Emptying the colon before inserting the vehicle significantly reduces the peristaltic bowel movement, therefore limiting the vehicle movement. In addition, relying only on the peristaltic movement restricts the area under observation, especially in large spaces such as the stomach and colon.

Another significant disadvantage of a passively driven *in vivo* video device is the fact that the capsule is constantly transmitting pictures for as long as it is in the body, even when it is not needed. Such continuous operation is inefficient and consumes a lot of energy.

Furthermore, passive devices have the disadvantage of the lack of control over the movement and general behavior of the device within the body. An external operator cannot easily control such movement, nor can the operator easily manage the behavior of the device within the body. Therefore, the device may enter an undesirable location, and/or otherwise behave in a less than optimal manner for the type of diagnostic procedure which is being performed.

SUMMARY OF THE INVENTION

The background art does not teach or suggest a device or system for actively controlling the movement of an *in vivo* vehicle introduced into a subject. The background art also does not teach or suggest such control which is based on changes in the magnetic field or electric field vectors produced by an external electromagnetic source, by extracorporeal devices equipped with electromagnetic sources or both of these types of control. The background art also does

not teach or suggest a system or method for controlling an *in vivo* vehicle via changes in the magnetic or electric field vectors from outside of the body, without a direct mechanical or physical connection to the vehicle. Lastly, the background art does not teach or suggest an algorithm for estimating the position and orientation of the vehicle. The background art also 5 does not teach or suggest that combinations of force and field measurements can be used to calculate the vehicle position and orientation.

The present invention overcomes these deficiencies of the background art by providing a device and a system for mobilizing, rotating and maneuvering an *in vivo* vehicle introduced into a subject by extracorporeal devices which control the position and motion of such a vehicle 10 by detection and modulation of the strength and direction of magnetic field vector of the vehicle. This invention preferably induces magnetic field changes with specific characteristics over time. The changes that result from the vehicle movement are measured and used to calculate the location and/or movement and/or orientation of the vehicle.

One exemplary embodiment of the present invention is to use one or more pulses in the 15 electromagnetic field (if used) to induce magnetic field changes. These pulse(s) preferably are time dependent, for calculating the location and/or movement of the vehicle. Since the response of the magnetic material of the vehicle to these pulse(s) is linear according to the activating pulse(s), and therefore has the same time dependence, the signal can be separated from the noise for locating the vehicle.

20 Preferably, the present invention provides a device and a system for mobilizing, rotating and maneuvering an *in vivo* vehicle by remote activation of force and moment of applied magnetic or electromagnetic fields. Application of force and moment on the magnet (or material that is magnetized or magnetizable) which is associated with the vehicle enables remote control of the vehicle's movement along all axes and all rotations around any given axis.

25 It is therefore provided, in accordance with a preferred embodiment of the present invention, a vehicle which is introduced into a luminary space of the body and which consists of an element that may be controlled by a controlling device outside of the body. The vehicle can also travel passively through the body lumen via peristaltic motion.

30 Additionally, the present invention discloses the use of an external magnetic or electromagnetic field for activation, generation of electromotive force (emf) and generation of magnetic flux changes which move, rotate, monitor and direct the magnet-containing vehicle in different directions in order to perform various kinds of tasks as described herein below.

In accordance with another preferred embodiment of the invention, the magnetic system of the *in vivo* vehicle may optionally and preferably be implemented according to one of the following configurations: as an integral part of the original vehicle; as an integral part of the original vehicle, but upon introduction into the subject, the magnet is released from the vehicle 5 as a tethered separate entity, such that the connecting element between the vehicle and the magnet can optionally serve as an antenna; as a separate entity tethered to the vehicle, in which the connecting element between the vehicle and the magnet can again optionally serve as an antenna; and as at least a partial exterior coating of the vehicle.

The magnetic system of the vehicle may optionally feature sintering magnetic material 10 or bonded material. This bonded magnetic material may optionally compose part of a biodegradable container, magnetic powder or magnetic particles, that dissolves with time, thereby allowing the removal of the magnetic substance from the body. For this configuration, the bond is preferably dissolvable, dispersible or otherwise soluble in an aqueous solution. After dissolving, the magnetic material is preferably in a powder form. The attractive force of 15 the individual particles of powder is very low and they can move freely, thereby being capable of changing geometric dimensions according to the dimensions of the surrounding structure.

In the configuration where the magnetic material covers all or part of the outer surface of the vehicle and the internal structure of the vehicle is protected by a layer of ferromagnetic material, then a magnetic field inside the vehicle is preferably not produced; this feature 20 protects the internal sub-systems of the vehicle.

Moreover, in accordance with another preferred embodiment of the invention, one or more capacitors can be installed into the body of the vehicle, which can be charged by an internal battery. In this embodiment, movement of the vehicle is achieved by applying an electric field on the electric charge of the capacitor(s). This may be accomplished with or 25 without a permanent magnet in the extracorporeal controlling unit.

Additionally, the present invention also relates to the combination between an external magnetic field and an internal permanent magnet integrated into the vehicle which would enable, in addition to the guidance and monitoring of the vehicle, other uses such as: measurement of the vehicle's location (via a tracking system) by calculating the changes in 30 magnitude and position of the magnetic field vector produced by the *in vivo* vehicle, and the changes in the force exerted on the coils of the tracking system (if present); and performing triggering actions such as activating and/or initializing and/or shutting down activities of the

vehicle's systems, in which the triggering activities may optionally be based on vehicle location or on any other meaningful parameter during the diagnostic procedure.

One advantage of the present invention is its ability to control the direction and speed of the vehicle in large spaces, i.e. the stomach, small intestine, colon and other abdominal as well 5 as pelvic spaces. In addition, by employing the present invention, it is possible to accurately control the position of the vehicle in an empty space, thus enabling a clear field of observation of the lumen and surfaces. The present invention also enables the guidance of one or more vehicles to a specific anatomical area when a more focused observation is required.

In another preferred embodiment of the invention, the vehicle is able to report its 10 position while inside the subject and can be easily detected upon passing a particular location in the body of the subject (patient), for example when exiting the body of the subject. This embodiment may optionally be implemented with at least one reed switch, which is a device that is sensitive to magnetic fields, and transmits a signal upon sensing such a field. When the reed switch becomes activated, the vehicle is near that switch, such that if the reed switch is 15 optionally placed near the location of interest, the vehicle can optionally be detected as it passes that location (for example, as it exits the body).

Additionally, in another preferred embodiment of the invention, the system includes an array of reed switches that define the location of the vehicle in the body. A two-dimensional array of such switches may optionally be placed on (adjacent but external to) the patient's body. 20 As the vehicle moves through the body, certain reed switches are activated. The geometrical center of the activated switches represents the position of the vehicle.

Moreover, in another preferred embodiment of the invention, during the use of the vehicle, energy can be saved, thus reducing the power consumption. The power saving can reduce the volume of the energy source needed in the vehicle, leaving more volume for other 25 elements. Timing of vehicle functions can optionally be accomplished by one or more of: time measurement; measuring the change in the pH and/or the concentration of electrolytes in the vehicle's immediate environment; pressure changes in the vehicle's immediate environment (i.e. the muscle of the ileo-cecal valve, local pressure changes, and so forth; and through an outside element, such as a reed switch for example. Pressure changes may optionally be 30 measured through a pressure sensitive capacitor or resistor, for example.

In accordance with another preferred embodiment of the invention, other functions can be included in the repertoire of the vehicle's utilities. These functions may optionally include one or more of: histology and sampling; fluid concentration sampling; local surgical

procedures; and drug delivery. These functions are optionally and more preferably performed by activation of the function in the vehicle, most preferably through the external control system of the present invention (as described in greater detail below), which would in turn activate some type of mechanical, electronic, electrical, optical, or chemical component(s) or combination thereof to perform the function.

Finally, in another preferred embodiment of the invention, magnetic or ferromagnetic beads or particles can be coated with a pharmaceutical compound for concentrated delivery to a specific body part via the extracorporeal control system. This particulate drug delivery system could optionally be injected into the blood or into an appropriate location and concentrated in that location for optimal effect via detection and modulation of the magnetic field vectors of the magnetic particles.

It should be noted that although the following description is directed toward the use of the present invention in the GI tract, this is for the purposes of illustration only and is not intended to be limiting in any way, as the present invention is suitable for use in any bodily cavity, space, vessel, organ or other non-solid section of the body.

Hereinafter, the term "magnet" includes soft and hard magnets, magnetic material, material that is magnetized and material that is magnetizable.

Hereinafter, the phrase "managing the vehicle" includes at least one of maneuvering, locating, mobilizing, controlling, monitoring (the vehicle) and activating at least one vehicle function.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a general schematic diagram for depicting the elements of the system and their layout;

Figure 2 is a schematic diagram for depicting the vehicle's magnetic system connected to the vehicle by a connecting element;

Figure 3 is a schematic diagram for depicting the vehicle's magnetic system inside the vehicle;

Figure 4 is a schematic diagram for depicting several possible configurations of the vehicle's magnetic system inside the vehicle or coating the outer surface of the vehicle;

Figure 5 is a schematic diagram for depicting the system for controlling and maneuvering the vehicle in the subject's colon;

Figure 6 is a schematic diagram for depicting the detection and motion control systems combined in a single element, showing that the field generator units may also optionally be used as detectors, while the field generating/detector units are preferably distributed on a flexible material and are preferably connected to the computerized control unit;

5 **Figure 7** is a schematic diagram for depicting the detection and motion control subsystems as separate elements distributed on a flexible material, while the detection and motion control subsystems are preferably connected to separate computerized control units;

Figure 8 is a schematic diagram for depicting a system for detecting the vehicle inside the body via Hall effect probes or pressure detectors;

10 **Figure 9** is a block diagram outlining the interactions of various parts of the extracorporeal generator and detector units;

Figure 10 is a flow chart of the steps involved in measuring and calculating the magnetic field vector of the vehicle and subsequently activating the vehicle; and

15 **Figure 11** is a schematic diagram of the calculation of the vector between the detecting element and the vehicle.

DETAILED DESCRIPTION OF THE INVENTION

The present invention discloses a device and a system for mobilizing, rotating and maneuvering an *in vivo* vehicle introduced into a subject by extracorporeal devices. Preferably, 20 the present invention provides a device and a system for mobilizing, rotating and maneuvering an *in vivo* vehicle by remote activation of force and moment of an applied magnetic or electromagnetic field.

A magnet, optionally made of any suitable biologically compatible magnetic, magnetized or magnetizable material, is installed inside or coats the outside of a vehicle, or is 25 attached to it by a connecting element. If the magnet is located within a sealed portion of the vehicle or is otherwise sealed, then optionally the magnet may be constructed of a less biologically compatible, or even a biologically incompatible, material.

Preferably, if the magnet is constructed of an alloy, the magnetic alloy is composed of one or more of Neodymium-Boron-Iron (NdBFe), Samarium Cobalt (SmCo) or other similar 30 compounds. The magnet can optionally be made of any permanent (hard) magnetic or ferromagnetic (soft) material that is magnetized under the influence of a magnetic or an electromagnetic field. The magnet's mass and physical properties include magnetization

direction and magnetization strength that enable the movement, rotation and maneuvering of the vehicle.

For management of the vehicle, preferably including at least one of movement, rotation, activation of a function and/or other types of control of the vehicle in the body of the subject, an 5 extracorporeal magnetic or electromagnetic field is preferably used. This magnetic source consists of a permanent magnet, an electromagnet or an electromagnet with soft magnetic material or any combination thereof.

In addition, the extracorporeal electromagnet may be composed of several coils that create a magnetic field or fields in various directions and with various gradients. In one 10 configuration, each coil in the electromagnet can be operated separately. In another configuration, each group of coils in the electromagnet can optionally be operated synchronously and also separately. Different currents can feed each coil and/or each group of coils. Similarly, the force vector (power and direction) applied on the external magnetic field source is measured, and used as feedback to control the status between the *in vivo* permanent 15 magnet and the external magnetic field source. The same coils can optionally and preferably be used to calculate the vehicle's location.

The measurement and tracking functions of the extracorporeal navigating system may 20 optionally and preferably be accomplished by: an electromagnet used for maneuvering the vehicle; a coil or more preferably a set of coils, capable of measuring magnetic field strength in a plurality of, but more preferably all, directions; Hall effect devices; a pressure measuring device; or a combination thereof; in which these elements are more preferably connected to a computerized control system.

A Hall effect device measures the magnetic field strength. This device changes the 25 electrical potential on the device when exposed to a magnetic field. This potential is measured and the result is converted to units for measuring a magnetic field.

The pressure-measuring device may optionally be implemented as follows. When an 30 electrical current in a coil is exposed to a magnetic field, a force acts on the coil. The coil creates pressure on its physical support, which can be measured. Calibration of the system enables the pressure to be translated to a measurement of the magnetic field, which can then optionally and preferably be used to calculate the vehicle position, for example.

The principle feature of the invention is the ability, via detection and generation of magnetic field vectors, to guide and maneuver the vehicle by an extracorporeal control unit, without the requirement for a physical connection between the vehicle and the control unit. The

extracorporeal guidance aiming may optionally be performed in one or more ways, for example by following a pre-determined and/or programmed route, according to the anatomical structure of the organ in which the vehicle is situated. In this option, the software program preferably receives feedback from the tracking system. The software program can optionally and 5 preferably correct mistakes, can limit the force applied on the vehicle to avoid damage to the tissue, and more preferably may activate procedures to re-locate the vehicle if it gets lost.

Another option is to use real time guidance, performed by the operator, according to information received from the vehicle. Alternatively, real time guidance may optionally be performed according to information received from any other imaging system (X-rays, US, MRI, 10 CT, etc), which can optionally be gathered before or during the diagnostic procedure involving the present invention, or any combination thereof.

The mode of external remote guidance and/or monitoring may also activate or enable other functions. The external remote guidance preferably enables the navigation of the vehicle in different directions in the observed area.

According to preferred embodiments of the present invention, the *in vivo* vehicle has 15 one or more preferred but optional features which allow it to be moved, turned, diverted and aimed at any angle. The electromagnetic receiving/signaling system of the vehicle may be composed of an electric dipole element or a magnetic element which forms an integral part of the vehicle or may be a separate element tethered to the vehicle by a connecting element. In the 20 integrated configuration, the magnetic element may be composed of a permanent magnetic ring or disk inserted into the vehicle, a permanent magnetic coating covering part or all of the exterior of the vehicle or a bonded magnetic material coating part or all of the vehicle's exterior. Alternatively, the magnetic element may be composed of ferromagnetic material which may coat part or the entirety of the vehicle's exterior. In addition, the magnetic element 25 may be composed of a permanent, bonded and/or ferromagnetic materials. The direction of the magnetic field of the magnetic element inside the vehicle may be axial, or parallel to the diameter (diametrical) in a case where the vehicle's geometry is round i.e. cylinder, disk, and/or ring shaped or a combination thereof.

In one tethered configuration, the magnetic element is connected to the vehicle upon 30 introduction into the patient, but is released from the vehicle at a certain stage in the diagnostic procedure and remains connected to the vehicle. In another preferred tethered configuration, the tethered magnet is introduced into the patient as such.

- The vehicle may also contain an electric circuit such that force can be applied to the vehicle through the electronic circuit when the vehicle is in a magnetic field. The electric circuit can be installed in the vehicle in place of the permanent magnet or in addition to it. Additionally, the vehicle may also contain capacitors which may be charged by a power source.
- 5 The capacitor or capacitors can be installed in the vehicle in place of the permanent magnet or in addition to it.

According to other optional but preferred embodiments of the present invention, there is provided a method for detecting the location of the vehicle and more preferably for also controlling the movement of the vehicle. First, a matrix of detectors are attached to the patient

10 or placed close to the patient. The matrix can be composed of Hall effect probes, coils which serve as probes or combinations of these elements. For example, the magnetic field may optionally be measured with a Hall effect probe, as previously described. Alternatively, the field may optionally be measured according to the force acting on a coil when current flows through it, or alternatively by measuring the potential on a coil when a time dependent magnetic

15 field is applied to it. This measurement enables the magnetic field caused by the vehicle to be calculated, such that the position of the vehicle can be calculated.

The probe detects at least one directional component of the magnetic field at any point of the matrix but may also be able to detect up to three directional components of the magnetic field. For a matrix composed of Hall Effect probes, it is possible to detect both time dependent

20 and time independent magnetic fields. For a matrix composed of coils, only a time dependent field can be detected directly, while the time independent field can be calculated from the force measurements.

For locating the vehicle, five parameters should preferably be calculated, namely three coordinates with respect to the detector matrix center and two orientation angles of the

25 magnetization with respect to coordinate system defined on the detection matrix. At least five measurements of the magnetic field of the vehicle are needed to extract this parameter providing that the distance and the orientation of detectors within the matrix and the strength and the direction with respect to the vehicle of the magnetization are known. The extraction of the five parameters is done by best fit of the known formula of the magnetic field at a point of

30 distance (d_x, d_y, d_z) from a magnetic dipole.

For example: Let x_m, y_m, z_m be the distance of a detector m from the center of the matrix, x, y, z the location of the vehicle, R_m be the distance of the vehicle from detector m and m_z is the z component of the vehicle magnetization. Therefore,

$$R_m = \sqrt{(x_m - x)^2 + (y_m - y)^2 + (z_m - z)^2}$$

Then the magnetic field at the point m is

$$B_x^m = \frac{3m_z(x_m - x)(z_m - z)}{R_m^5}$$

$$5 \quad B_y^m = \frac{3m_z(y_m - y)(z_m - z)}{R_m^5}$$

$$B_z^m = \frac{3m_z[(z_m - z)^2 + R_m^2]}{R_m^5}$$

Similar equations for m_y , and m_x can be written by changing z to y and z to x in the above equations.

- 10 The unknowns are x, y, z, m_z and m_y ; the measured quantity are B_x^m , B_y^m , B_z^m . Using a best fit program the best estimation of x, y, z, m_z , m_y , and m_x and the error in the estimated value is then calculated. Then from the knowledge of the magnetization of the vehicle consistency can be checked i.e.

$$M = \sqrt{m_z^2 + m_y^2 + m_x^2}$$

- 15 M is the measured vehicle magnetization.

When a force measurement is used (coil detectors), the following equation is employed:

$$\vec{F}_m = \oint I_m \vec{ds} \times \vec{B}$$

- where I_m is the current in the m coil, B is calculated as in the equation above and the integral is along the coil. I_m , s and M are known F_m is measured. The current in the coil may change from coil to coil in the matrix to get the best measurement. Then a best-fit program is used to estimate position and orientation of the vehicle. Combinations of force and field measurement can be used to calculate the vehicle position and orientation. In the preferred embodiment the number of measurements is larger than the number of unknowns, as this should reduce the error. Minimally, at least as many measurements as unknowns are required for the calculation.

- 25 Reference is now made to Figure 1 which illustrates the major elements of the system and their layout including an extracorporeal navigation system 18 for guiding an *in vivo* vehicle 19 within the patient 17. As shown, extracorporeal navigation system 18 is optionally in direct physical contact with at least a portion of patient 17 although this is not necessary, as physical

proximity is sufficient. For example, vehicle 19 could optionally be used for diagnostic imaging techniques and/or other medical procedures.

Reference is now made to Figure 2 which depicts the tethered magnetic element configuration 20 of the vehicle where a separate magnetic element 12 is tethered to vehicle 19 by a connecting element 13. It should be noted, for the purposes of description for these drawings, that the term "magnetic element" includes any type of magnet, which as previously described may include one or more of a magnet (whether soft or hard), magnetized material or magnetizable material, or a combination thereof. Connecting element 13 is an exemplary tether for magnetic element 12, which is preferably flexible but alternatively is rigid. Connecting element 13 and vehicle 19 may optionally be constructed of a metal, an alloy, a plastic or a combination of materials, but may not necessarily be constructed of the same or similar materials. Connecting element 13 and/or vehicle 19 may optionally be from hundreds of microns to a few millimeters in length, although it should be noted that size is not necessarily a limiting factor. Rather, the dimensions of connecting element 13 and/or vehicle 19 are optionally and preferably chosen according to the dimensions of the body space or spaces in which vehicle 19 travels.

Magnetic element 12 may optionally be smaller than vehicle 19. One advantage of this embodiment is that magnetic element 12 does not need to fit within vehicle 19, such that a larger size of magnetic element 12 may optionally be used.

Reference is now made to Figure 3 which depicts an integrated vehicle configuration 30, where a magnetic element 22 is integrated into the body of vehicle 19.

Reference is now made to Figures 4a-4f, in which several types of vehicles are shown. It should be noted that the same reference numbers denote the same or similar elements.

As shown in Figure 4a, a vehicle 200 preferably features an inserted magnet 204, optionally in the form of a ring or disk, which is more preferably permanently installed. A magnetization direction 202 is shown.

As shown in Figure 4b, the electromagnetic receiving/signaling system of a vehicle 210 may optionally be composed of a magnetic dipole element 212. In this case, vehicle 210 is powered by an electromagnetic field imposed on the vehicle from the extracorporeal device.

As shown in Figure 4c, a vehicle 220 may optionally feature a magnetic element 222 which is implemented as a partial or full covering of the exterior of vehicle 220, or even as a partial or full exterior structure for vehicle 220. The degree of the magnetic field which is generated or which is capable of being generated by magnetic element 222 may optionally and

preferably be varied in a plurality of different portions of vehicle 220. Each portion may optionally have a different direction of magnetization in order to optimize the control of the movement of vehicle 220.

Similarly, for Figure 4d, a vehicle 230 may optionally feature a partial or full exterior structure 221 made from bonded material, optionally and more preferably with inserted magnet 204, again optionally in the form of a ring or disk, which again is more preferably permanently installed.

In Figure 4e, a vehicle 240 is shown with partial or full exterior structure 221 made from bonded material optionally as the sole magnetic element. For either implementation, the bond can optionally be made of dissolvable or non-dissolvable material, and can also optionally partially fill the interior volume of the vehicle.

In Figure 4f, a vehicle 250 is shown with a partial or full exterior structure 252 made from a permanently magnetic or ferromagnetic material. Figure 4g shows a vehicle 260 with a partial or full exterior structure 253 made from a ferromagnetic material.

Reference is now made to Figure 5 which describes an exemplary system 50 according to the present invention for controlling and maneuvering the vehicle in the subject's colon. As previously noted, although the following description is directed toward the use of the system of the present invention in the GI tract, this is for the purposes of illustration only and is not intended to be limiting in any way, as the present invention is suitable for use in any bodily cavity, space, vessel, organ or other non-solid section of the body.

Vehicle 51 can be maneuvered within colon 54, and can optionally and preferably be focused on a particular field of view 52. Vehicle 51 is preferably guided by one, and more preferably a plurality of external guidance elements 53 as shown. Each external guidance element 53 could optionally be a coil, reed switch, or Hall effect sensor, for example. If a plurality of external guidance elements 53 is used, then vehicle 51 can more easily be located. The plurality of external guidance elements 53 is preferably distributed about the body of the patient (not shown) and then calibrated. The location of external guidance elements 53 and their number depends at least partially upon the accuracy of management of vehicle 51 that is desired and the activity to be performed.

Reference is now made to Figure 6 which illustrates the detection and motion control systems combined in a single component 60. The field generator units and detector units are contained in one element 61, such that the magnetic field is both produced and detected by element 61. The field generator units can optionally operate on the principle of magnetic flux or

electromagnetic field production. The field generating/detector units (elements 61) are preferably distributed on a flexible material 65 and are more preferably connected via power and information buses 62 to a computer control unit 64. Flexible material 65 may optionally be in the form of a blanket or sheet which can be wrapped around at least a portion of the patient.

5 Reference is now made to Figure 7 which depicts a different configuration for the detection and motion control subsystems as a separated system 70, such that the magnetic field is generated and detected by different components of system 70. A field generation subsystem computer control unit 71 and a detecting subsystem computer control unit 72 are located in different locations in system 70. As in the combined system depicted in Figure 6, a field 10 generating element 73 can optionally operate on the principle of production of a magnetic flux or electromagnetic field. Field generating element 73 and a detecting element 74, of which a plurality of each such element are shown for the purposes of description only, are connected to their respective computer control units by power and information buses 62. This implementation is preferred to avoid cross-talk between the generation and detection of the 15 magnetic field, and may also optionally provide greater sensitivity.

Reference is now made to Figure 8 which illustrates a prototype detector unit 80. One or 20 more measuring devices 81 are connected to one or more types of field detectors 82. These detectors may include Hall effect probes, pressure detectors, devices for measuring Doppler or devices for measuring laser Doppler effects. Measuring device(s) 81 are preferably connected to a switching or indicating device (not shown). The switching or indicating device may optionally be composed of one or more devices such as an individual reed switch or arrays of reed switches, flip switch, electromagnetic, electronic optical or mechanical flag type indicator, LED or memory device which can respond to a signal above or below preset thresholds to locate the vehicle, activate a function or turn off a certain function of the vehicle. Measuring 25 devices 81 and field detectors 82 are preferably attached to a flexible sheet 83, for being wrapped around at least a portion of the patient for example. Flexible sheet 83 may also optionally be implemented as a belt and/or as a rigid board of less flexible material for holding these components.

Reference is now made to Figure 9, which depicts a block diagram outlining the 30 interactions of various parts of the extracorporeal generator and detector units in an exemplary system 90 according to the present invention. A computer 92 preferably features a display 94 for displaying information to the user about the operation of system 90, more preferably as a graphical user interface (GUI). The user is preferably able to send one or more commands to

computer 92 for controlling the behavior of system 90 through a user interface 100, which is optionally and more preferably implemented as a joystick.

A detection control unit 96 preferably receives one or more commands from computer 92 for controlling one or more detection elements 106. Each detection element 106 is 5 preferably capable of detecting a magnetic field, and may optionally be implemented as previously described. Detection control unit 96 optionally and more preferably sends data to computer 92 concerning signals and/or data received from detection element 106.

A magnetic generator control unit 102 is also preferably in communication with computer 92 and also preferably receives one or more commands from computer 92 for 10 controlling the function of one or more magnetic sources 104. Magnetic sources 104 include a magnet and may optionally be implemented as previously described, for example as one material and/or component, or a plurality of materials and/or components.

A power supply 98 optionally supplies power to computer 92, detection control unit 96 and magnetic generator control unit 102, and may optionally also supply power to one or both 15 of detection elements 106 or magnetic sources 104. Power supply 98 may optionally be implemented as a plurality of such power supplies (not shown).

Reference is now made to Figure 10 which illustrates a flow chart of the stages involved in measuring and calculating the magnetic field vector of the vehicle and subsequently activating the vehicle. Application of the magnetic field is performed by the generator unit and 20 detection of the signals emitted from the vehicle is performed by the detection unit. The calculations are performed by the computer, which preferably has sufficient power to integrate many complex signals simultaneously.

First, the magnetic field is applied and/or an existing magnetic field is detected. Next, the detector units in the extracorporeal device preferably detect magnetic signals from the 25 vehicle to locate the vehicle. As shown, after the vehicle has been located in the body, next the vector force is calculated for the magnetic field vectors of the vehicle. After performing a best fit calculation, the x, y, z, m_x, m_y, m_z parameters are estimated (see previous equations for a description). After checking the consistency of the calculation, the current is measured and the force of magnetization (F_m) is then calculated. Next, from these calculations, one or more of the 30 vehicle position, movement and orientation are preferably determined.

If one or more operator control commands are received, for example from a human operator, then the operator commands are preferably translated in relation to the location of the vehicle, and more specifically are translated in relation to the magnetic field of the vehicle.

Next, the vector force to be applied to perform the operator command is calculated and the force is then applied. Next, at least one of a new vehicle position, movement and orientation is preferably determined. This information is preferably then displayed to the operator.

5 Reference is now made to Figure 11 which provides a schematic description 110 of the calculation of the vector between a plurality of extracorporeal detecting elements 120 and a vehicle 112. In this diagram, vehicle 112 is situated in a body lumen or cavity 114. The vehicle's magnetization vector 122 is detected by detector elements 120 through the skin 118 via interactions with the detector units' magnetic field vectors 116. These signals are preferably
10 processed according to the procedure outlined in Figure 10.

Having now generally described the invention, the same will be more readily understood through reference to the following examples, which are provided by way of illustration and are not intended to be limiting of the present invention.

15

EXAMPLES

Example 1: Gastrointestinal (GI) use of the invention

The present invention is conceived as being a viable alternative to endoscopy, especially in diagnostic or therapeutic procedures in the esophagus, stomach, small intestine, large 20 intestine and rectum. The invention allows the medical personnel to directly observe the epithelial lining of the GI tract and to carry out medical procedures such as tissue sample collection for histological examination, liquid sampling for microscopic examination and culturing and small surgical procedures such as removal of suspicious polyps in the large intestine. These procedures can be carried out with less danger to the patient since no physical 25 connection between the vehicle and the extracorporeal navigating device is necessary. The invention is useful for carrying out the above functions in the diagnosis of or as part of the treatment of malignant, nonmalignant, infectious, and genetic diseases as well as birth or developmental defects.

30 Example 2: Application of the invention in the bronchus

The present invention is conceived as being a viable alternative to bronchoscopy. The invention allows the medical personnel to directly observe the epithelial lining of the bronchi and to carry out medical procedures such as tissue sample collection for histological

examination, liquid sampling for microscopic examination and culturing and small surgical procedures. These procedures can be carried out with less discomfort and danger to the patient since no physical connection between the vehicle and the extracorporeal navigating device is necessary. The invention is useful for carrying out the above functions in the diagnosis of or as 5 part of the treatment of malignant, nonmalignant, infectious, and genetic diseases as well as birth or developmental defects.

Example 3: Applications of the invention in the abdomen:

The present invention is conceived as being an additional tool used in laparoscopy or as 10 a viable alternative to laparoscopy. As mentioned in the previous examples, the vehicle, under the control of the extracorporeal navigating device, can perform small surgical procedures. The invention could therefore be launched from a laparoscopic instrument into the abdomen to perform a certain task or could actually be used in place of the laparoscope in certain indications such as the destruction of kidney stones, gallstones, or other pathological crystalline 15 deposits in other organs. Alternatively, the invention could be used for directly observing organs and tissues in the abdominal space and for carrying out medical procedures such as tissue sample collection for histological examination, liquid sampling for microscopic examination and culturing and surgical procedures, as part of the diagnosis or treatment of malignant, nonmalignant, infectious, and genetic diseases as well as birth or developmental 20 defects.

Example 4: Drug delivery

The present invention is conceived as being a means for directly controlling and optimizing drug delivery to a specified tissue or organ. The pharmaceutical compound can be 25 encapsulated into liposomes or any other suitable form for delivery to the target organ and magnetic particles can be impregnated into the structure of the delivery device in such a way so that the extracorporeal navigating system can concentrate them into the desired location. Alternatively and preferably, magnetic particles can be coated with the therapeutic or structures containing the therapeutic such as liposomes or microspheres and these can serve as the drug 30 delivery vehicle. Such a drug delivery system could be administered orally, intravenously or parenterally depending on the indication as determined by those skilled in the art.

Having now fully described certain preferred embodiments of this invention, it will be appreciated by those skilled in the art that the same can be performed within a wide range of equivalent parameters, and conditions without departing from the spirit and scope of the invention and without undue experimentation.

5

While this invention has been described in connection with specific embodiments thereof, it will be understood that it is capable of further modifications. This application is intended to cover any variations, uses, or adaptations of the inventions following, in general, the principles of the invention and including such departures from the present disclosure as come within known or customary practice within the art to which the invention pertains and as may be applied to the essential features hereinbefore set forth as follows in the scope of the appended claims.

All references cited herein, including journal articles or abstracts, published or 15 unpublished U.S. or foreign patent applications, issued U.S. or foreign patents, or any other references, are entirely incorporated by reference herein, including all data, tables, figures, and text presented in the cited references. Additionally, the entire contents of the references cited within the references cited herein are also entirely incorporated by reference.

Reference to known method steps, conventional method steps, known methods or 20 conventional methods is not in any way an admission that any aspect, description or embodiment of the present invention is disclosed, taught or suggested in the relevant art.

The foregoing description of the specific embodiments will so fully reveal the general nature of the invention that others can, by applying knowledge within the skill of the art (including the 25 contents of the references cited herein), readily modify and/or adapt for various applications such specific embodiments, without undue experimentation, without departing from the general concept of the present invention. Therefore, such adaptations and modifications are intended to be within the meaning and range of equivalents of the disclosed embodiments, based on the teaching and guidance presented herein. It is to be understood that the phraseology or terminology herein is for the purpose of description and not of limitation, such that the 30 terminology or phraseology of the present specification is to be interpreted by the skilled artisan in light of the teachings and guidance presented herein, in combination with the knowledge of one of ordinary skill in the art.

WHAT IS CLAIMED IS:

1. A system for managing an *in vivo* vehicle in a subject, comprising:
 - a. a magnet being physically associated with the vehicle;
 - b. an extracorporeal magnetic source for producing a magnetic field for being applied to said magnet, said extracorporeal magnetic source being located outside of the subject;
 - c. a detector for detecting a magnetic field from said magnet, said detector being located outside of the subject; and
 - d. a control module for receiving a magnetic field measurement from said detector and for managing the vehicle according to said magnetic field measurement.
2. The system of claim 1, wherein managing the vehicle includes at least one of maneuvering, rotating, locating, mobilizing, controlling, monitoring and activating at least one vehicle function.
3. The system of claims 1 or 2, wherein application of said magnetic field comprises application of a gradient of said magnetic field.
4. The system of any of claims 1-3, wherein said magnet includes an electromagnet.
5. The system of claim 4, wherein said extracorporeal magnetic source features a plurality of coils to measure at least one of a distance and a location of the vehicle, by measuring at least one time dependent change of said magnetic field resulting from movement of the vehicle.
6. The system of any of claims 1-3, wherein said magnet includes a soft magnet.
7. The system of any of claims 1-3, wherein said magnet includes a hard magnet.
8. The system of any of claims 1-3, wherein said magnet includes a ferromagnetic material.

9. The system of any of claims 1-3, wherein said magnet is a permanent magnet, comprising at least one material for producing a permanent magnet having permanent magnetization.

10. The system of any of claims 1-3, wherein said permanent magnet is made from at least one material being magnetized in a magnetic field.

11. The system of claims 9 or 10, wherein said permanent magnet is part of an outer surface of the vehicle.

12. The system of claim 11, wherein an entire exterior surface of the vehicle is said permanent magnet.

13. The system of any of claims 9-11, further comprising a connecting element for connecting said permanent magnet to the vehicle.

14. The system of claim 13, wherein said connecting element is used as an antenna to send and receive signals to and from the vehicle.

15. The system of any of claims 1-14, wherein the force and directional vectors between said magnet and said extracorporeal magnetic source are used to calculate a location of the vehicle.

16. The system of any of claims 1-15, wherein the vehicle's path inside the body is preplanned.

17. The system of claim 16, wherein the vehicle's preplanned path relies on the anatomical structure of the examined organ or examined area.

18. The system of claims 16 or 17, wherein the vehicle's path inside the body is controlled at least partially according to information received about a location of the vehicle.

19. The system of claim 18, wherein said information is received from at least one of a separate imaging system or diagnostic system.

20. The system of any of claims 16-19, wherein the vehicle's path inside the body is controlled at least partially according to information received directly from the vehicle.

21. The system of any of claims 1-20, further comprising a receiver for receiving at least one of a data input or a command, said receiving being located in the vehicle.

22. The system of any of claims 1-21, wherein activation of a function of the vehicle is triggered by a timer.

23. The system of any of claims 1-21, wherein activation of a function of the vehicle is triggered by a distance counter.

24. The system of claim 23, wherein said activation of said function of the vehicle is triggered by distance measurement according to the Doppler principal.

25. The system of claim 23, wherein said activation of said function of the vehicle is triggered by distance measurement performed by a laser Doppler.

26. The system of any of claims 1-21, wherein activation of a function of the vehicle is triggered, per time frame and/or anatomic position, by an element outside the subject.

27. The system of any of claims 1-21, wherein activation of a function of the vehicle is triggered by signals originating from at least one of said extracorporeal magnetic source and said magnetic field from the vehicle.

28. The system of any of claims 1-21, wherein activation of said function of the vehicle is triggered by a change of pH at the area where the vehicle is located.

29. The system of any of claims 1-21, wherein activation of said function of the vehicle is triggered by a change of at least one electrolyte concentration at the location where the vehicle is located.

30. The system of any of claims 1-21, wherein activation of said function of the vehicle is triggered by a change of pressure on the vehicle.

31. The system of any of claims 1-30, wherein the vehicle contains elements that perform histological tests.

32. The system of any of claims 1-31, wherein the vehicle contains an element for performing a local surgical procedure.

33. The system of any of claims 1-32, wherein a single Hall probe or an array of Hall probes measures the vehicle's location inside the subject.

34. The system of any of claims 1-33, wherein a pressure applied by or on the vehicle is measured by a pressure-measuring element, and a change in said magnetic force caused by said pressure is sensed by said detector.

35. The system of claim 34, wherein said pressure is also used to calculate an inclination angle of the vehicle.

36. The system of any of claims 1-35, wherein a single reed switch or an array of reed switches is used to determine a location of the vehicle.

37. The system of any of claims 1-36, wherein said detector and said extracorporeal magnetic source are assembled on a bandage that is attached to the subject.

38. The system of any of claims 1-37, wherein said detector indicates when the vehicle passes a predetermined location.

39. The system of claim 38, wherein said detector comprises at least one a reed switch for determining when the vehicle has passed said predetermined location.

40. The system of claim 38, wherein said detector comprises an array of reed switches for determining when the vehicle has passed said predetermined location.

41. The system of any of claims 38-40, wherein an indicator is used to indicate when the vehicle passes said predetermined location.

42. The system of claim 41, wherein said indicator is selected from the group consisting of an electromagnetic, electronic, optical and mechanical flip switch.

43. The system of claim 41, wherein said indicator is selected from the group consisting of an electromagnetic, electronic, optical and mechanical flag type indicator.

44. The system of any of claims 41-43, wherein said indicator is a LED or lamp.

45. The system of any of claims 1-44, wherein said magnet is at least partially composed of a powder of magnetic material.

46. The system of any of claims 1-45, wherein said vehicle further comprises one or more of an imaging element, a functioning element, a power source and a transmitting element.

47. A system for managing an *in vivo* vehicle in a subject, wherein managing includes at least determining a location of the vehicle in the subject, the system comprising:

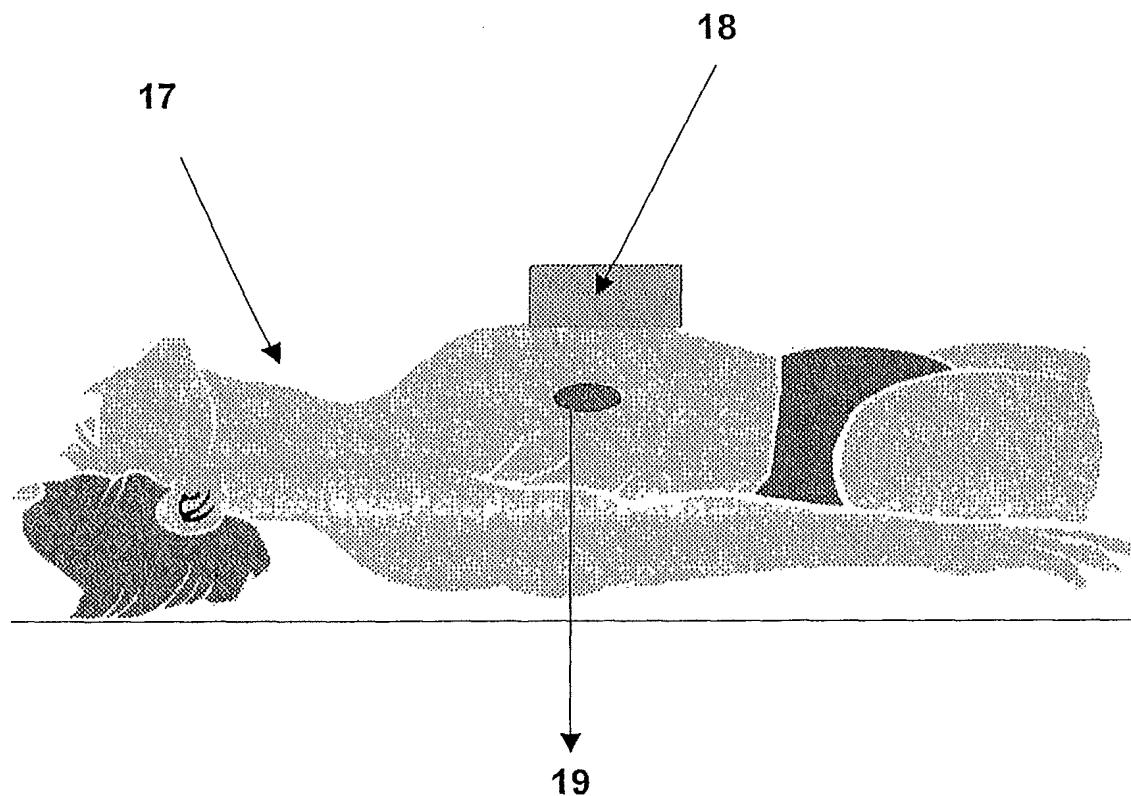
- a. a magnet being physically associated with the vehicle;
- b. an extracorporeal magnetic source for producing a magnetic field for being applied to said magnet, said extracorporeal magnetic source being located outside of the subject; and
- c. a detector for detecting a magnetic field from said magnet, said detector being located outside of the subject, such that a location of the vehicle is determined according to said magnetic field measurement.

48. A system for managing an *in vivo* vehicle in a subject, comprising:

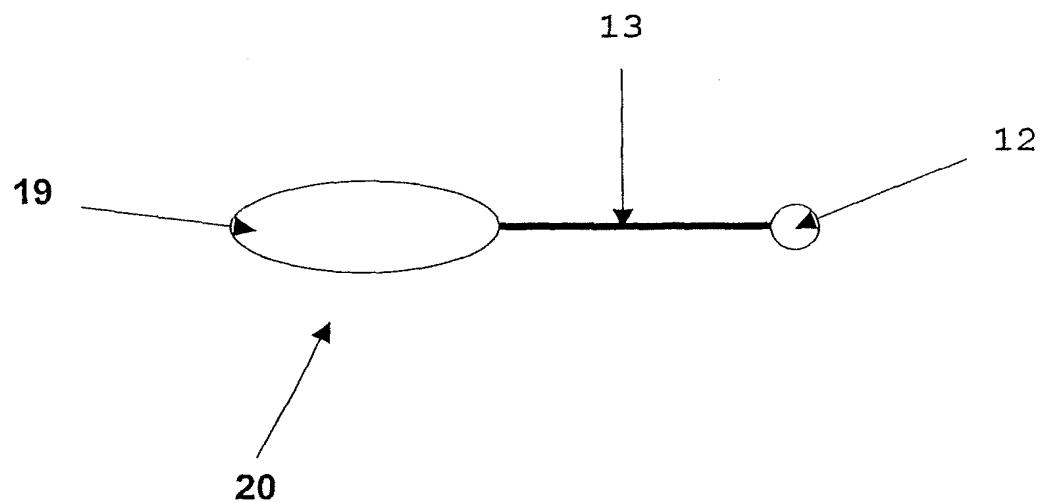
- a. a magnet being physically associated with the vehicle;
- b. an extracorporeal magnetic source for producing a magnetic field for being applied to said magnet, said extracorporeal magnetic source being located outside of the subject;
- c. a detector for detecting a magnetic field from said magnet, said detector being located outside of the subject; and
- d. a control module for receiving a magnetic field measurement from said detector and for managing the vehicle according to said magnetic field measurement, wherein said managing is performed by modulating at least one of a strength and a direction of said magnetic field from said magnet.

49. The system of claim 48, wherein said control module modulates said magnetic field by inducing a plurality of changes in said magnetic field with specific characteristics over time.

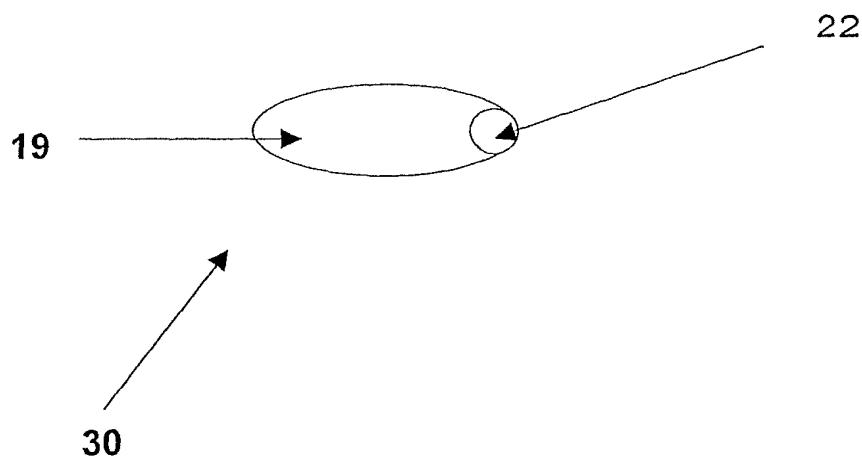
50. The system of claims 48 or 49, wherein said extracorporeal magnetic source is an electromagnet and said magnetic field is an electromagnetic field, and said control module causes said extracorporeal magnetic source to produce at least one pulse in said electromagnetic field to induce said changes in said magnetic field.

Figure 1

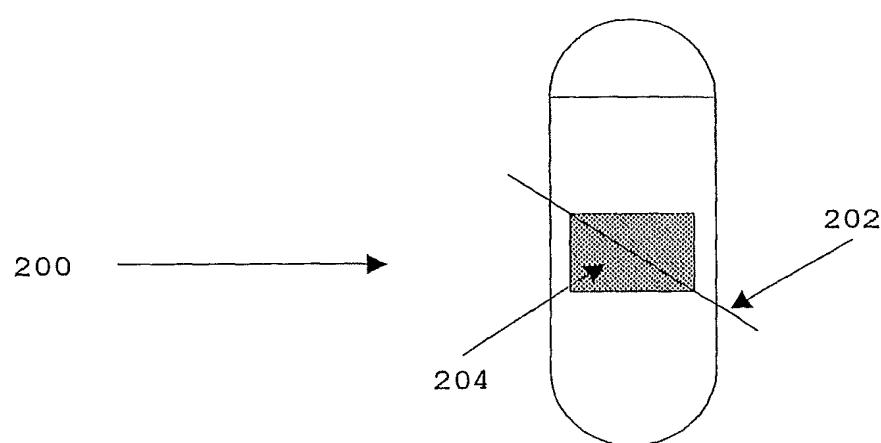
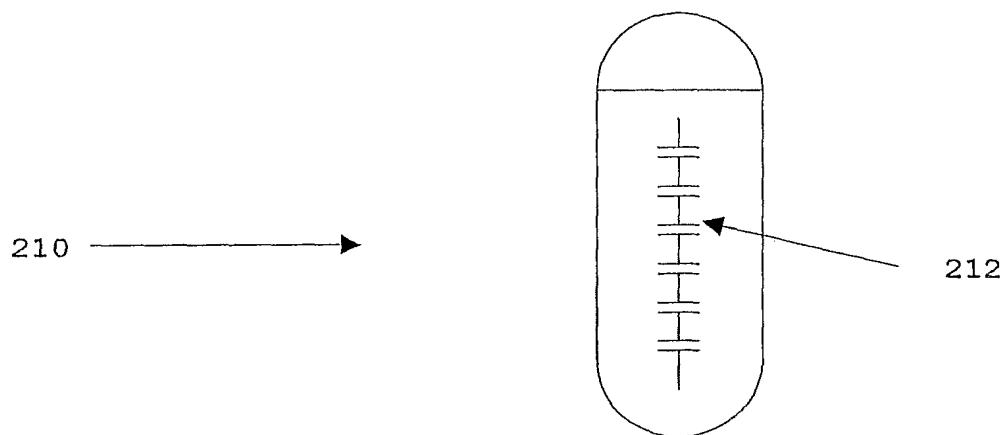
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Figure 2

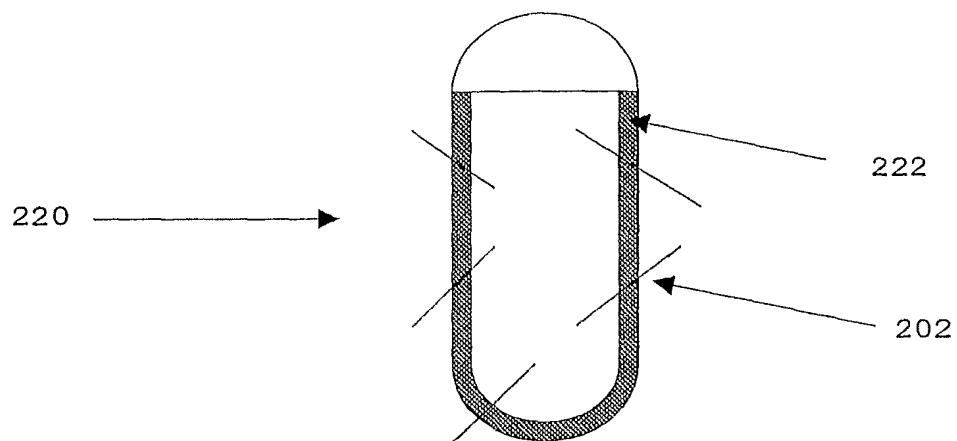
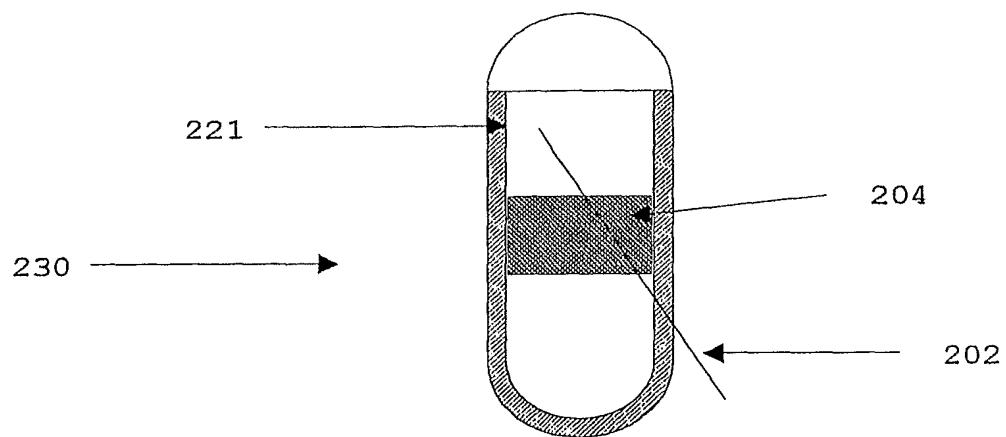
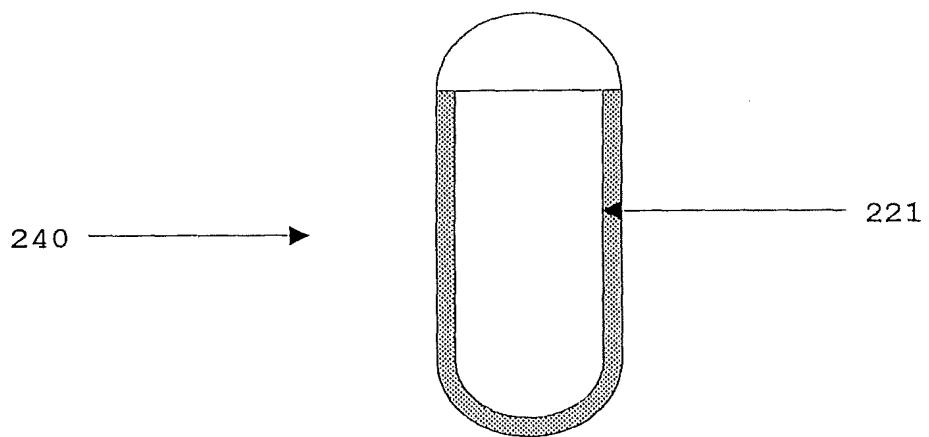
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Figure 3

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Figure 4aFigure 4b

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Figure 4cFigure 4dFigure 4e

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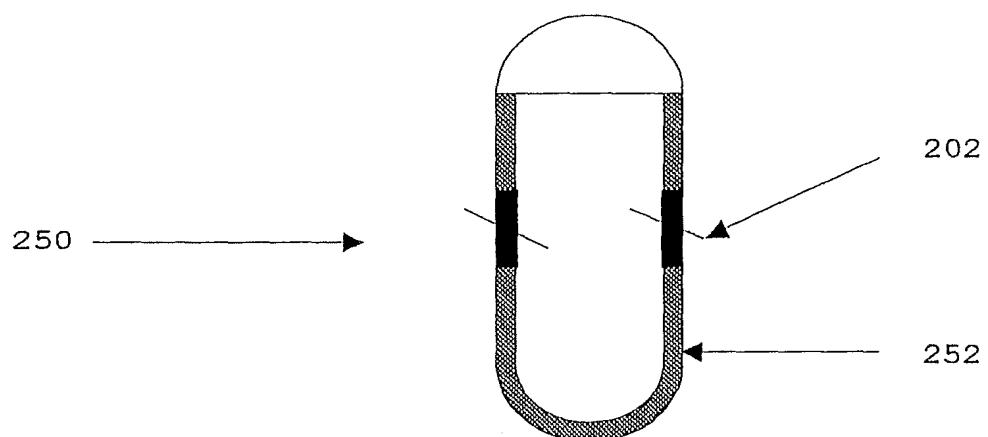
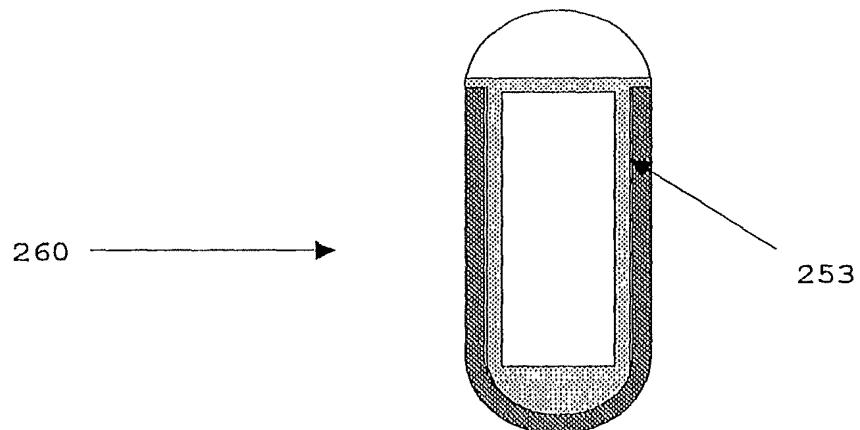
Figure 4f**Figure 4g**

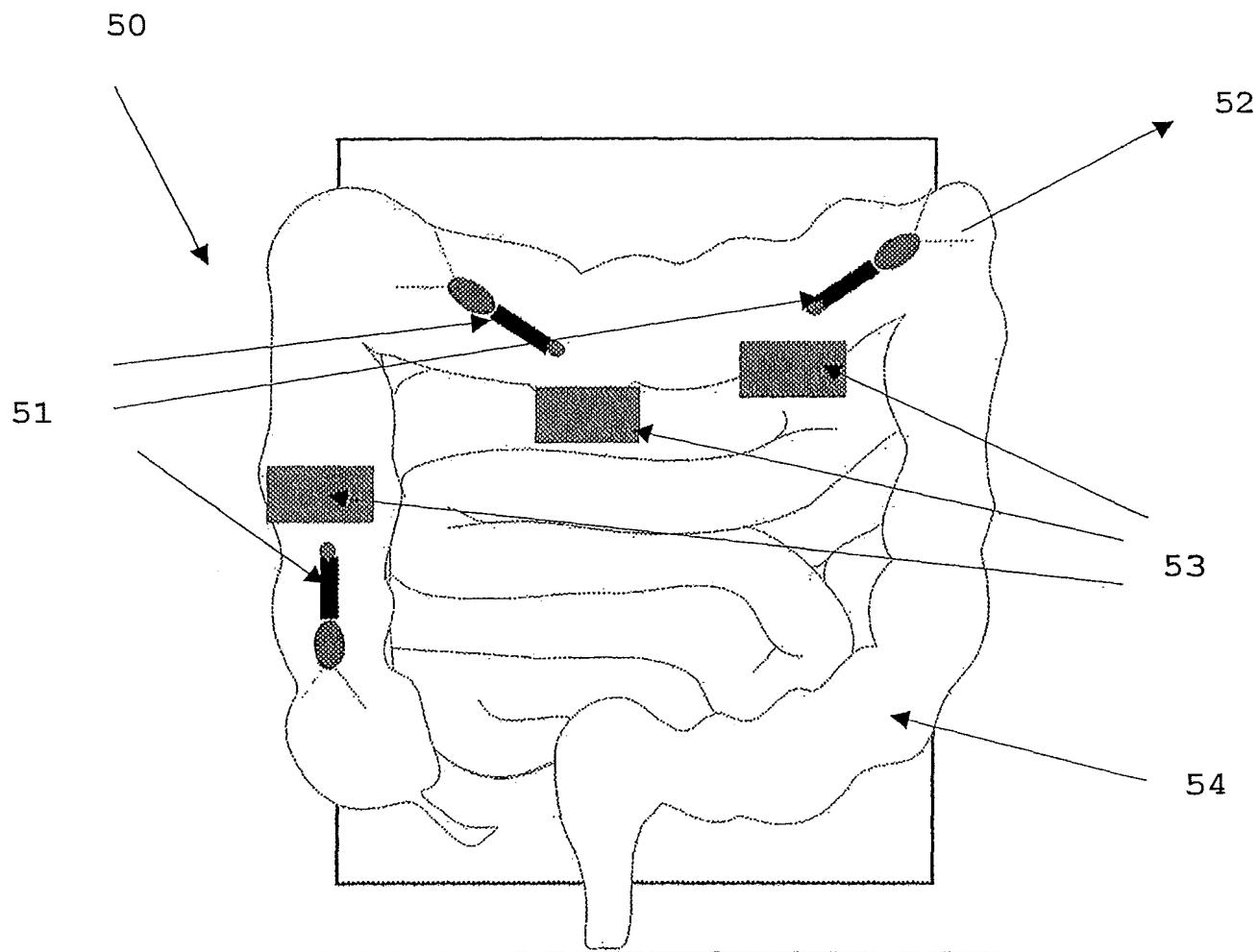
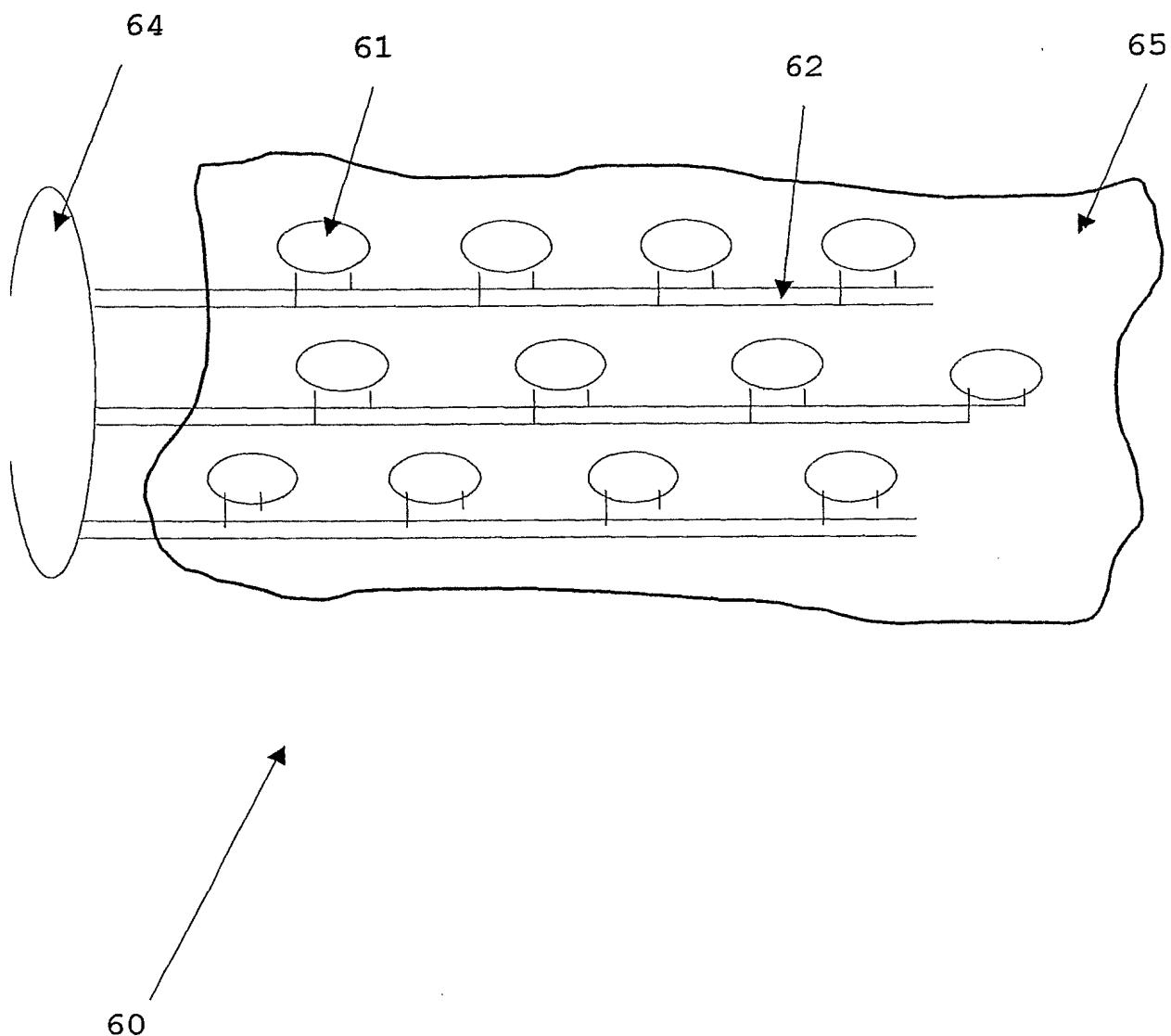
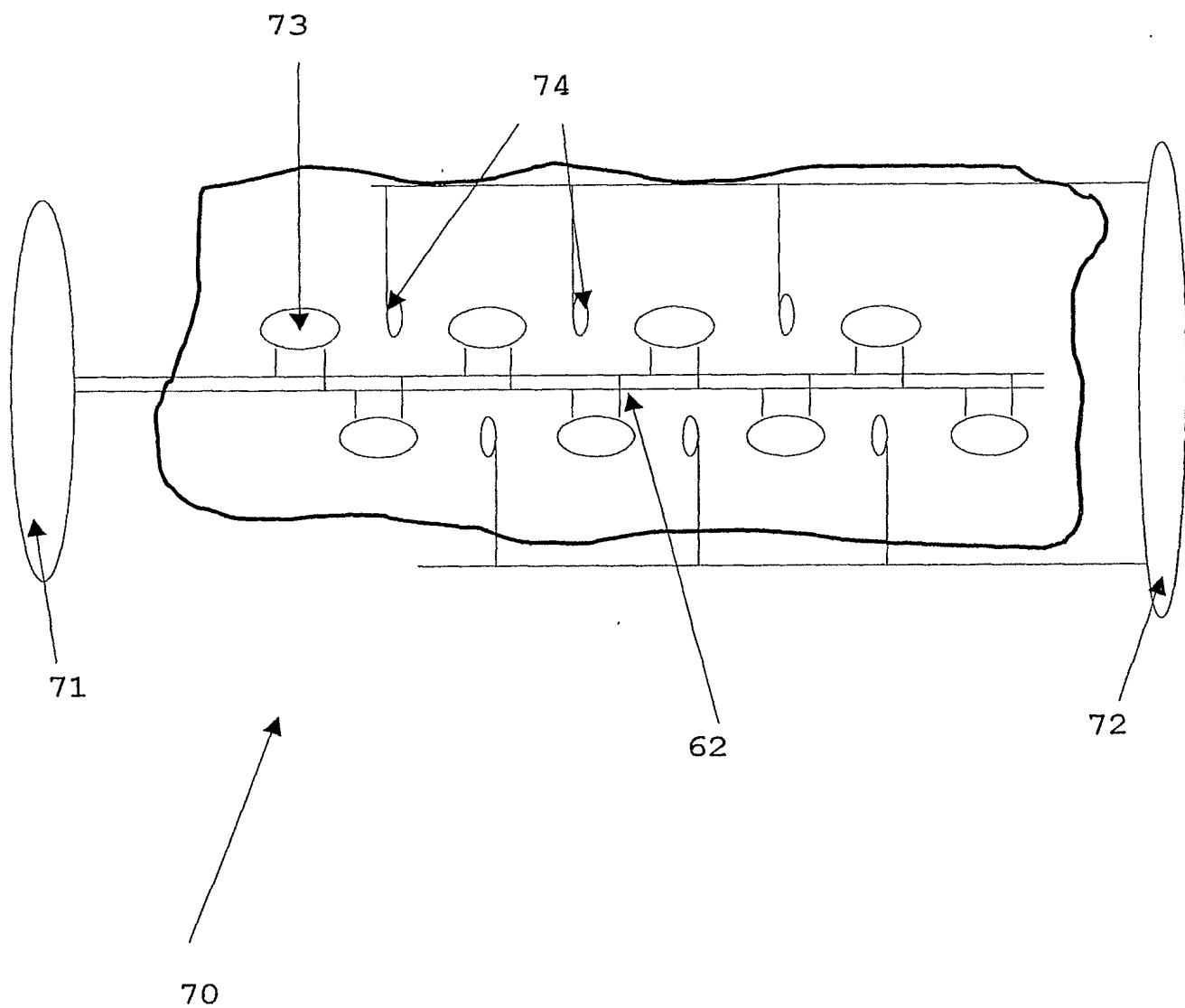
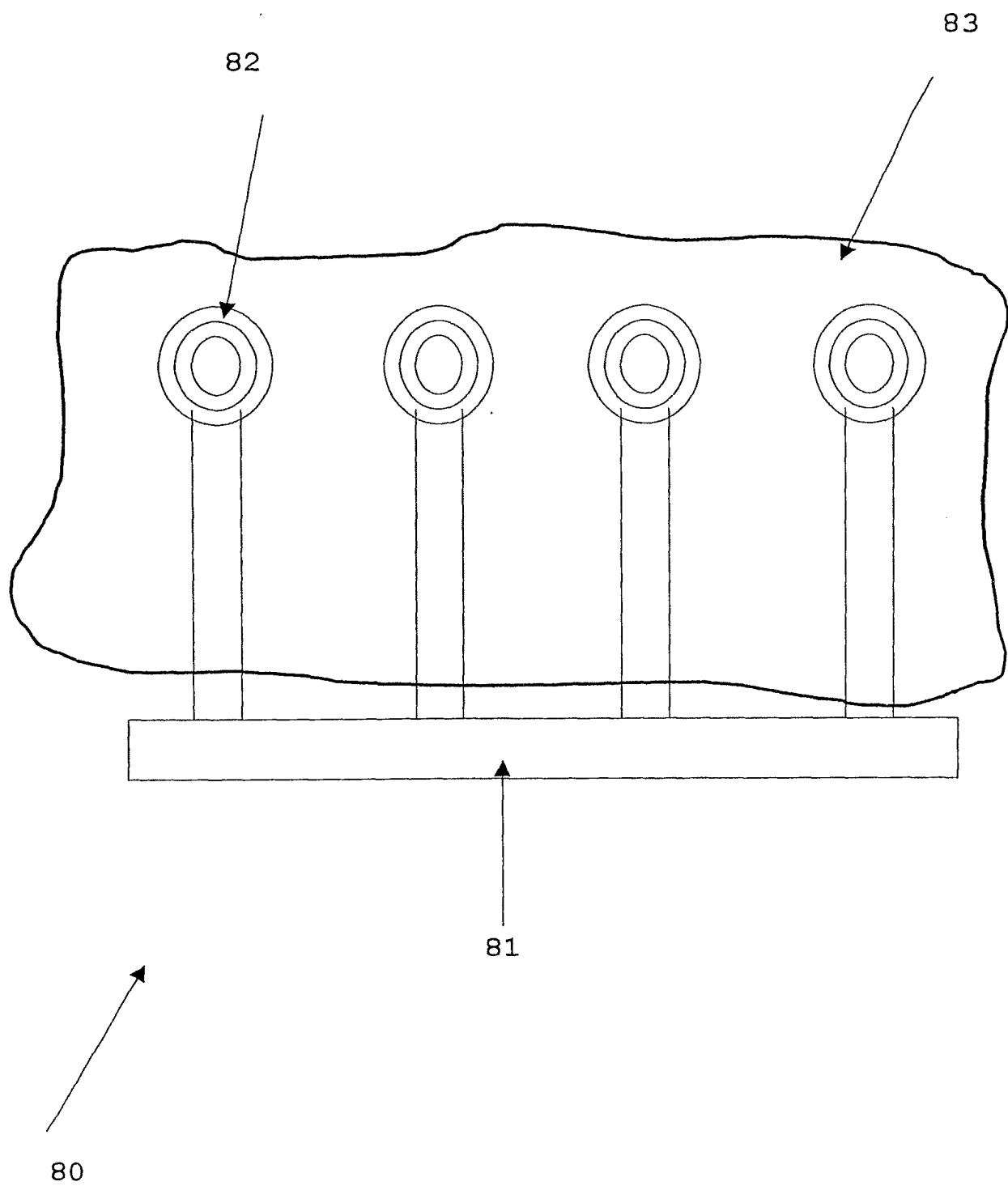
Figure 5

Figure 6

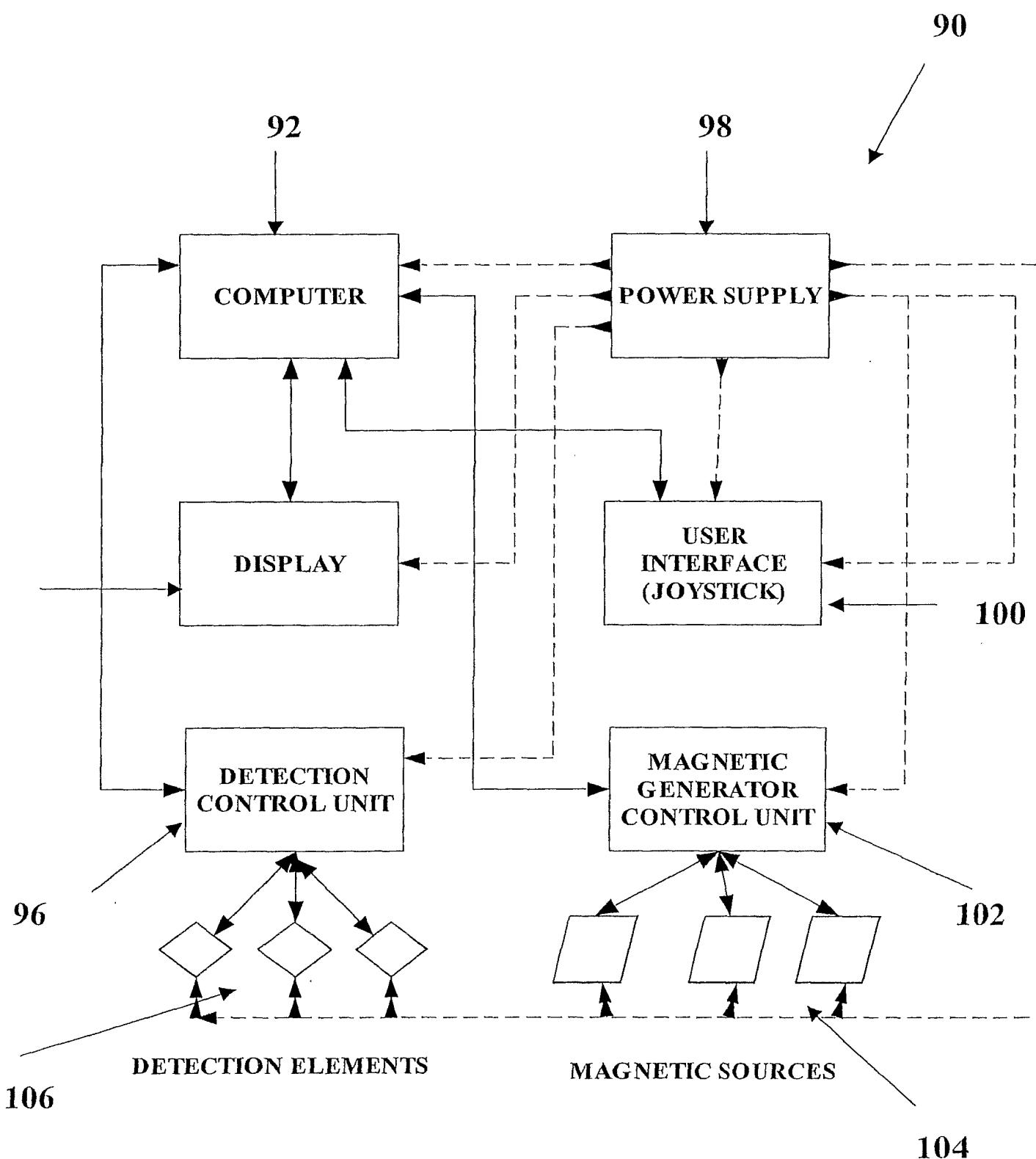
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Figure 7

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Figure 8

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Figure 9

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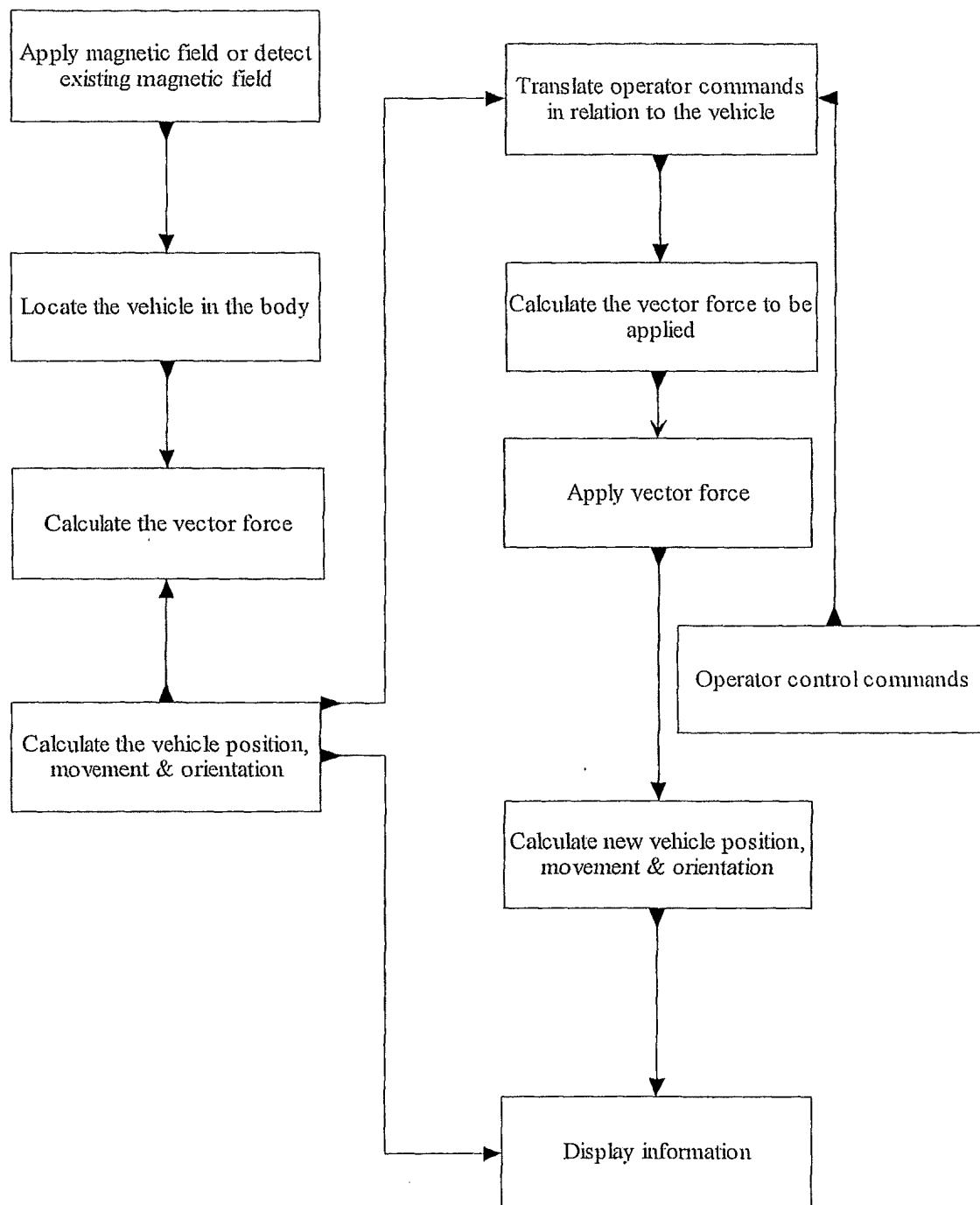
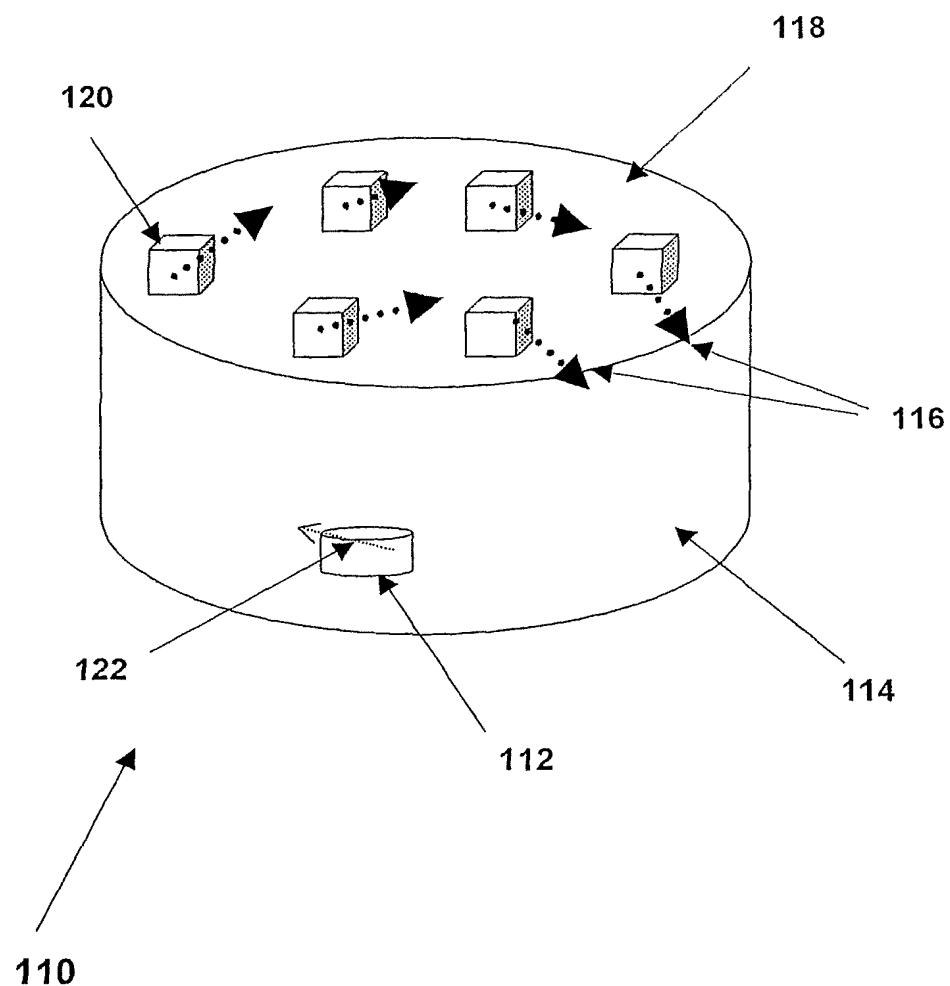
Figure 10

Figure 11

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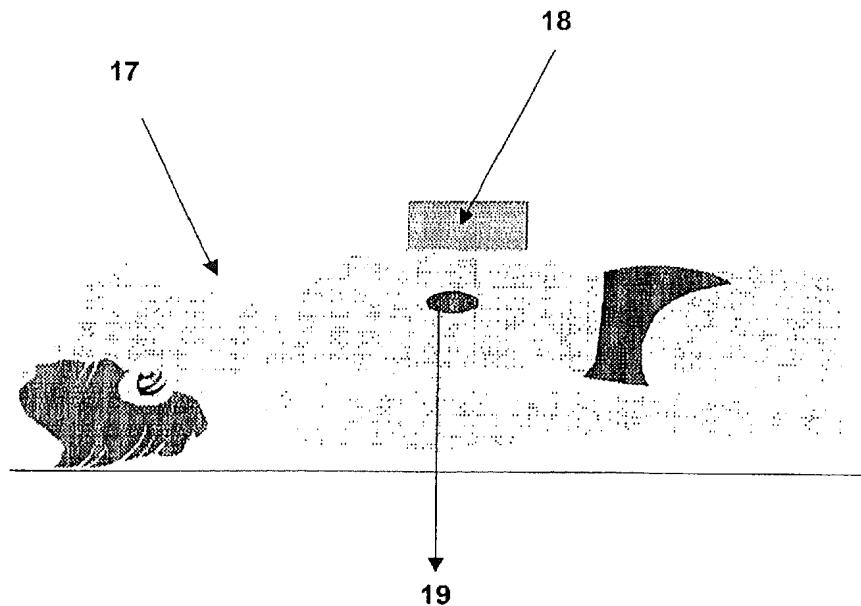
— with international search report

[Continued on next page]

(54) Title: NAVIGATING AND MANEUVERING OF AN IN VIVO VEHICLE BY EXTRACORPOREAL DEVICES



WO 02/082979 A3



(57) **Abstract:** A device for mobilizing, rotating and maneuvering an in vivo vehicle introduced into a subject by extracorporeal devices which control the position and motion of such a vehicle by detection and modulation of the strength and direction of the electromagnetic field vector of the vehicle. This invention employs a series of pulses, with specific characteristics over time, to induce magnetic field changes. The changes that result from the vehicle movement are measured and used to calculate the location and movement of the vehicle. A system and method for controlling the movement of the vehicle are also provided.



— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

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IPC 7 A61B5/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 681 260 A (YAMAGUCHI TATSUYA ET AL) 28 October 1997 (1997-10-28)	1-4, 6-10, 13, 21, 31-33, 36, 38, 39, 45-50
Y	column 15, line 55 -column 19, line 17; figures 22-27 column 25, line 61 -column 26, line 21 column 34, line 54 -column 35, line 16 ----- US 5 558 091 A (ACKER DAVID E ET AL) 24 September 1996 (1996-09-24) column 8, line 42-60; figure 1 ----- -----	5, 11, 15-20, 27, 30-32
Y		5, 15

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 02/00286

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 278 077 A (MIZUMOTO MORIHIDE) 14 July 1981 (1981-07-14) column 2, line 28-37 ----	27
Y	US 5 638 819 A (MANWARING KIM H ET AL) 17 June 1997 (1997-06-17) abstract ----	16-20
Y	DE 43 13 843 A (STM MEDTECH STARNBERG) 24 November 1994 (1994-11-24) column 6, line 33 -column 7, line 27; figure 3 ----	11,31,32
Y	EP 0 667 115 A (ISRAEL STATE) 16 August 1995 (1995-08-16) column 5, line 3-7 ----	30
A	WO 99 18852 A (UNIV CALIFORNIA ;ARENSON RONALD L (US)) 22 April 1999 (1999-04-22) page 10, line 2-12 -----	13,14

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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